DRUGS ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED ACCORDING TO DIRECTIONS

4041. Misbranding of various drugs. U. S. v. James Allen Nolen (Radium Springs Sanitarium). Plea of nolo contendere. Defendant fined $2,000 and placed on probation for 1 year. (F. D. C. No. 30592. Sample Nos. 70301–K, 70304–K, 70722–K, 70723–K, 76931–K to 76943–K, incl., 85796–K to 85799–K, incl.)

INFORMATION FILED: July 24, 1951, Northern District of Oklahoma, against James Allen Nolen, trading as the Radium Springs Sanitarium, Salina, Okla.

ALLEGED SHIPMENT: Between the approximate dates of December 11, 1949, and April 15, 1950, from the State of Oklahoma into the States of Missouri, Kansas, and Texas, of quantities of *tablets for pain and nerves, rheumatism and gland tablets, laxative for stomach and kidneys, V E tonic tablets and capsules, tablets for rheumatism, nerves, and diabetes, powder for the treatment of cancer, douche powder, tablets for "sick" stomach, tablets for sore throat, tonsil disorders, "flue," and fever, capsules for the condition known as change of life, tablets and capsules for the treatment of cancer,* and *tablets for nervousness and sleeplessness.*

PRODUCT: Analyses disclosed that the *tablets for pain and nerves* contained aspirin, acetophenetidin, caffeine, and starch; that the *rheumatism and gland tablets* contained sodium salicylate, potassium iodide, vitamin B_1, and riboflavin; that a portion of the *laxative for stomach and kidneys* contained magnesium sulfate, magnesium acetate, potassium acetate, an emodin-bearing drug such as cascara, reducing sugar, and alcohol, and that another portion of the laxative contained magnesium sulfate, potassium acetate, alcohol, reducing sugar, and emodin; that the *V E tonic tablets* contained a large amount of yeast and calcium carbonate; that the *V E tonic capsules* contained chiefly yeast and lecithin; that the *tablets for rheumatism, nerves, and diabetes* contained salicylamide, vitamin B_1, and magnesium salicylate equivalent to salicylic acid; that the *powder for the treatment of cancer* contained bismuth subnitrate, colloidal aluminum hydroxide, activated charcoal, and the mucilaginous coating of blond psyllium seed; that the *tablets for "sick" stomach* contained bismuth subnitrate and phenobarbital; that the *tablets for sore throat, tonsil disorders, "flue," and fever* contained sulfathiazole, sugar, and starch; that the *capsules for the condition known as change of life* contained estrone, cornstarch, and lactose; that the *douche powder* contained boric acid, ammonium alum, berberine, and phenolic substances; that the *tablets for the treatment of cancer* contained lactose, cornstarch, and a trace of phenobarbital; that the *capsules for the treatment of cancer* contained calcium carbonate, sucrose, cornstarch, lactose, and animal tissues; and that the *tablets for nervousness and sleeplessness* contained phenobarbital, pentobarbital, starch, and calcium carbonate.

NATURE OF CHARGE: *Tablets for pain and nerves.* Misbranding, Section 502 (a), the statement on the label of the article which represented and suggested that the article would be efficacious in the cure, mitigation, and treatment of disorders of the nerves was false and misleading since the article would not be efficacious for such purposes; and, Section 502 (e) (2), the label of the article failed to bear the common or usual name of each active ingredient of the article, namely, aspirin, acetophenetidin, and caffeine.

Rheumatism and gland tablets. Misbranding, Section 502 (a), the statements on the label of the article which represented and suggested that the article would be efficacious in the cure, mitigation, and treatment of rheumatism and diseases of the glands were false and misleading since the article would not be efficacious for such purposes; and, Section 502 (e) (2), the label of the article failed to bear the common or usual name of each active ingredient of the article, namely, sodium salicylate, potassium iodide, and gelsemium extract.

Laxative for stomach and kidneys. Misbranding, Section 502 (a), the statement on the label of the article which represented and suggested that the article would be efficacious in the cure, mitigation, and treatment of diseases of the stomach and kidneys was false and misleading since the article would not be efficacious for such purposes; Section 502 (e) (2), the label of the article bore no statement containing the common or usual name of each active ingredient of the article, namely, epsom salt and cascara sagrada, and no statement of the quantity, kind, and proportion of alcohol present in the article; and, Section 502 (f) (1), the labeling of a portion of the article failed to bear adequate directions for use in the treatment of cancer, which was the disease for which that portion of the article was intended to be used. Further misbranding, Section 502 (f) (2), the labeling of the article failed to bear adequate warnings against use of the article in those pathological conditions where its use may be dangerous to health, in that the article was a laxative and should not be used when abdominal pain (stomach ache, cramps, and colic), nausea, vomiting (stomach sickness), or other symptoms of appendicitis are present, and the labeling of the article failed to bear a warning that it should not be used in the presence of such symptoms; and, further, the labeling of the article failed to bear adequate warnings against unsafe dosage and duration of administration, in such manner and form, as are necessary for the protection of users, in that frequent or continued use of the article may result in dependence upon laxatives to move the bowels, and its labeling failed to warn that frequent or continued use may have that result.

V E tonic tablets and capsules. Misbranding, Section 502 (a), the statements on the labels of the articles which represented and suggested that the articles would be efficacious in the cure, mitigation, and treatment of diabetes and that the articles possessed tonic properties were false and misleading since the articles would not be efficacious for such purposes and did not possess tonic properties; and, Section 502 (e) (2), the label of the *V E tonic tablets* failed to bear the common or usual name of the active ingredient of the article, namely, calcium carbonate.

Tablets for rheumatism, nerves, and diabetes. Misbranding, Section 502 (a), the statements on the label of the article which represented and suggested that the article would be efficacious in the cure, mitigation, and treatment of rheumatism, diabetes, and diseases of the nerves were false and misleading since the article would not be efficacious for such purposes; and, Section 502 (e) (2), the label of the article failed to bear the common or usual name of each active ingredient, namely, salicylamide and magnesium salicylate.

Powder for the treatment of cancer. Misbranding, Section 502 (e) (2), the label failed to bear the common or usual name of each active ingredient of the article, namely, bismuth subnitrate, colloidal aluminum hydroxide,

activated charcoal, and the mucilaginous coating of blond psyllium seed; and, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use in the treatment of cancer, which was the disease for which the article was intended to be used.

Tablets for "sick" stomach. Misbranding, Section 502 (a), the statements on the label of the article which represented and suggested that the article would be efficacious in the treatment of "sick" stomach were false and misleading since the article would not be efficacious for such purpose. Further misbranding, Section 502 (d), the article contained a chemical derivative of barbituric acid, phenobarbital, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the article failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming." Further misbranding, Section 502 (e) (2), the label of the article bore no statement containing the common or usual name of each active ingredient of the article, namely, phenobarbital and bismuth subnitrate; and, Section 502 (f) (1), the labeling of a portion of the article failed to bear adequate directions for use in the treatment of cancer, which was the disease for which that portion of the article was intended to be used.

Tablets for sore throat, tonsil disorders, "flue," and fever. Misbranding, Section 502 (a), the statements on the label of the article which represented and suggested that the article would be efficacious in the cure, mitigation, and treatment of sore throat, tonsil disorders, "flue," and fever were false and misleading since the article would not be efficacious for such purposes; Section 502 (e) (2), the label of the article failed to bear the common or usual name of the active ingredient of the article, namely, sulfathiazole; Section 502 (f) (2), the labeling of the article bore no warnings against use of the article in those pathological conditions where its use may be dangerous to health, and against unsafe dosage and methods and duration of administration; and, Section 502 (j), each tablet of the article contained 2 grains of sulfathiazole and was dangerous to health when used in the dosage and with the frequency and duration prescribed, recommended, and suggested in its labeling, namely, "let 1 tab dissolve on tongue each 1 or 2 hours till relieved."

Capsules for the condition known as change of life. Misbranding, Section 502 (a), the statement on the label of the article which represented and suggested that the article would be efficacious in the relief of the symptoms associated with the condition commonly known as change of life was false and misleading since the article would not be efficacious for such purpose; and, Section 502 (e) (2), the label of the article failed to bear the common or usual name of the active ingredient of the article, namely, estrone.

Tablets for nervousness and sleeplessness. Misbranding, Section 502 (d), the article contained a chemical derivative of barbituric acid, namely, phenobarbital, which derivative has been found to be, and by regulations designated as, habit forming; and the label of the article failed to bear the name, and quantity or proportion of such derivative and in juxtaposition therewith the statement "Warning—May be habit forming." Further misbranding, Section 502 (f) (1), the labeling of the article failed to bear adequate directions for use in the treatment of cancer, which was the disease for which the article was intended to be used.

Further misbranding, Sections 502 (b) (1) and (2), the *tablets for pain and nerves, rheumatism and gland tablets, laxative for stomach and kidneys, V E tonic tablets and capsules, tablets for rheumatism, nerves, and diabetes, powder for the treatment of cancer, tablets for "sick" stomach, tablets for sore throat, tonsil disorders, "flue," and fever, capsules for the condition known as change of life,* and *tablets for nervousness and sleeplessness* failed to bear labels containing the place of business and, in some instances, the name of the manufacturer, packer, or distributor; and such articles failed also to bear labels containing a statement of the quantity of the contents.

Douche powder and tablets and capsules for the treatment of cancer. Misbranding, Section 502 (f) (1), the label of the articles failed to bear adequate directions for use in the treatment of cancer, which was the disease for which the articles were intended to be used.

Further misbranding, Section 502 (a), the statement "Nolen M. D.," appearing on the label of a portion of the *laxative for stomach and kidneys,* and the statement "Dr. Nolen," appearing on the label of the *tablets for nervousness and sleeplessness* and on the label of a portion of the *rheumatism and gland tablets* and *tablets for "sick" stomach,* were false and misleading. Such statements represented and suggested that the defendant, James Allen Nolen, possessed the medical qualifications required for the practice of medicine in the State of Oklahoma and was licensed to practice medicine in that State, whereas the defendant did not possess such medical qualifications and was not licensed to practice medicine in such State.

DISPOSITION: November 21, 1951. The defendant having entered a plea of nolo contendere, the court fined him $2,000 and placed him on probation for 1 year.

VIOLATIVE SALES OF PRESCRIPTION DRUGS

4042. Misbranding of dextro-amphetamine sulfate tablets and sulfathiazole tablets. U. S. v. Griffin-Robertson Drug Co. and Gilbert C. Griffin and Marcus W. Robertson. Pleas of nolo contendere by individual defendants. Action against company dismissed. Each individual defendant fined $50. (F. D. C. No. 34316. Sample Nos. 46528–L to 46531–L, incl.)

INFORMATION FILED: December 5, 1952, Northern District of Mississippi, against the Griffin-Robertson Drug Co., a partnership, Corinth, Miss., and Gilbert C. Griffin and Marcus W. Robertson, partners in the partnership.

NATURE OF CHARGE: On or about June 21 and 22, 1952, while a number of *dextro-amphetamine sulfate tablets* and *sulfathiazole tablets* were being held for sale at the Griffin-Robertson Drug Co., after shipment in interstate commerce, the defendants caused quantities of the drugs to be dispensed without a prescription from a practitioner licensed by law to administer such drugs. This act of dispensing was contrary to the provisions of Section 503 (b) (1) and resulted in the dispensed drugs being misbranded.

DISPOSITION: February 11, 1953. Pleas of nolo contendere having been entered by the individual defendants, the court fined each individual $50. The court ruled that the action did not lie against a partnership and therefore dismissed the action against the partnership defendant.